

|  |  |                                       |                               |
|--|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)   | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>06275-150003 | Application No.<br>10/010,283 |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br>(37 CFR §1.98(b)) |  | Applicant<br>Carl-Axel Bauer et al.   |                               |
|  |  | Filing Date<br>November 13, 2001      | Group Art Unit<br>1617        |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |  |
|---|-----------|--|
| Examiner Initial  | Desig. ID | Document   |
|   | A1        | Ankerst <i>et al.</i> , "Tolerability of a high dose of budesonide/formoterol in a single inhaler in patients with asthma," <i>Pulm Pharmacol Ther.</i> , 16:147-51, 2003.   |
|   | A2        | Arvidsson <i>et al.</i> , "Inhaled formoterol during one year in asthma: a comparison with salbutamol," <i>Eur Respir J</i> , 4:1168-1173, 1991.   |
|   | A3        | Aubier <i>et al.</i> , "Salmeterol/Fluticasone propionate (50/500 µg) in combination in a Diskus® inhaler (Seretide®) is effective and safe in the treatment of steroid-dependent asthma," <i>Respir. Med.</i> 93:876-884, 1999.   |
|   | A4        | Bartow <i>et al.</i> , "Formoterol: An Update of its Pharmacological Properties and Therapeutic Efficacy in the Management of Asthma," <i>Drugs</i> , 55(2):303-322, 1998.   |
|   | A5        | Bond, "A strategy that works," <i>New Zealand Medical Journal</i> , p. 369, 28 August 1991.  |
|   | A6        | "The British Guidelines on Asthma Management 1995 Review and Position Statement," <i>Thorax</i> , 52(Suppl 1):S1-21, 1997.   |
|   | A7        | Collins <i>et al.</i> , "The Use of Corticosteroids in the Treatment of Acute Asthma," <i>Quarterly Journal of Medicine, New Series</i> , XLIV:259-73, 1975.   |
|   | A8        | Corren <i>et al.</i> , "Twelve-Week, Randomized, Placebo-Controlled, Multicenter Study of the Efficacy and Tolerability of Budesonide and Formoterol in One Metered-Dose Inhaler Compared with Budesonide Alone and Formoterol Alone in Adolescents and Adults with Asthma," <i>Clinical Therapeutics</i> , 29(5):823-843, 2007. |
|   | A9        | Costain <i>et al.</i> , "Guidelines for management of asthma in adults: I—chronic persistent asthma," <i>BMJ</i> , 301:651-653, 1990.  |
|   | A10       | Devidayal <i>et al.</i> , "Efficacy of nebulized budesonide compared to oral prednisolone in acute bronchial asthma," <i>Acta Paediatr</i> , 88:835-840, 1999.   |
|   | A11       | Ebden <i>et al.</i> , "Comparison of two high dose corticosteroid aerosol treatments, beclomethasone dipropionate (500 µg/day) and budesonide (1600 µg/day), for chronic asthma," <i>Thorax</i> , 41:869-874, 1986.  |
|   | A12       | Ellul-Micallef and Johansson, "Acute Dose-Response Studies in Bronchial Asthma with a New Corticosteroid, Budesonide," <i>Br. J. Clin. Pharmac.</i> , 15:419-422, 1983.  |
|   | A13       | Ellul-Micallef <i>et al.</i> , "Budesonide: A New Corticosteroid in Bronchial Asthma," <i>Eur J Respir Dis.</i> , 61:167-173, 1980.  |
|   | A14       | Engel <i>et al.</i> , "Single-dose inhaled budesonide in subjects with chronic asthma," <i>Allergy</i> , 46:547-553, 1991.   |
|   | A15       | Fanta <i>et al.</i> , "Glucocorticoids in Acute Asthma," <i>American Journal of Medicine</i> , 74:845-851, 1983.   |
|   | A16       | "FDA recommends easier-to-take asthma drug" <i>Florida Today</i> , Associate Press, November 24, 1999.   |
|   | A17       | "Foradil: Fast relief that lasts," Ciba-Geigy Limited, Switzerland, Medical and Pharmaceutical Information, 1993   |
|   | A18       | Hekking <i>et al.</i> , "Efficacy and tolerability of inhaled formoterol compared with inhaled salbutamol over three months", Symposium held during the 8th congress of the European Society of Pneumology, Freiberg, Germany, September 1989.   |
|   | A19       | Hett <i>et al.</i> , "Large-Scale Synthesis of Enanti- and Diastereomerically Pure (R,R)-Formoterol," <i>Org. Process Res. Dev.</i> , 2:96-99, 1998.   |

|  |                 |
|--|-----------------|
| Examiner Signature   | Date Considered |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |

|   |  |                                       |                               |
|---|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)  | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>06275-150003 | Application No.<br>10/010,283 |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary) |  | Applicant<br>Carl-Axel Bauer et al.   |                               |
|   |  | Filing Date<br>November 13, 2001      | Group Art Unit<br>1617        |
| (37 CFR §1.98(b))   |  |                                       |                               |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |   |
|---|-----------|---|
| Examiner Initial  | Desig. ID | Document  |
|   | A20       | Jackson <i>et al.</i> , "Benefit-Risk Assessment of Long-Acting $\beta_2$ -Agonists in Asthma," Drug Safety, 27(4):243-270, 2004.   |
|   | A21       | Kesten <i>et al.</i> , "A Three-Month Comparison of Twice Daily Inhaled Formoterol Versus Four Times Daily Inhaled Albuterol in the Management of Stable Asthma," Am Rev Respir Dis, 144:622-625, 1991.                             |
|   | A22       | Kumar <i>et al.</i> , "Transient Effect of Inhaled Fluticasone on Airway Mucosal Blood Flow in Subjects with and without Asthma," Am J Respir Crit Care Med, 161:918-921, 2000.   |
|   | A23       | Lampa <i>et al.</i> , "Antitracheobronchospastic Interaction <i>In Vitro</i> and <i>In Vivo</i> between Salbutamol and Flunisolide," Drugs Exptl. Clin. Res., XI(9):653-658, 1985.  |
|   | A24       | Li, "Key Points of the new asthma guidelines," The Journal of Respiratory Diseases, 18:823-838, 1997.   |
|   | A25       | McDonald <i>et al.</i> , "Evaluation of the combination inhaler of salbutamol and beclomethasone dipropionate in the management of asthma," Curr. Med. Res. Opin., 11(2), 1988.   |
|   | A26       | McFadden, "Inhaled Glucocorticoids and Acute Asthma: Therapeutic Breakthrough or Nonspecific Effect?," Am J Respir Crit Care Med, 157:677-678, 1998.  |
|   | A27       | Monthly Index of Medical Specialties (MIMS), Asthma, COPD, September 2007.  |
|   | A28       | Monthly Index of Medical Specialties (MIMS), Bronchodilators and anti-inflammatories, December 1991.  |
|   | A29       | Monthly Index of Medical Specialties (MIMS), Respiratory System, December, 1991.  |
|   | A30       | Moore <i>et al.</i> , "Long-acting Inhaled $\beta_2$ -Agonists in Asthma Therapy," Chest, 113:1095-1108, 1998.  |
|   | A31       | Nana <i>et al.</i> , "High-Dose Inhaled Budesonide May Substitute for Oral Therapy After an Acute Asthma Attack," Journal of Asthma, 35:647-655, 1998.  |
|   | A32       | National Asthma Education and Prevention Program, "Guidelines for the Diagnosis and Management of Asthma," Expert Panel Report 2 July 1997 No. 97-4051.   |
|   | A33       | Nyholm <i>et al.</i> , "Therapeutic advantages of twice-daily over four-times daily inhalation budesonide in the treatment of chronic asthma," Eur J Respir Dis, 65:339-345, 1984.  |
|   | A34       | The Patents Act 1953 Exhibit "CRWB1."   |
|   | A35       | The Patents Act 1953 Exhibit "CRWB3."   |
|   | A36       | The Patents Act 1953 Exhibit "CRWB4."   |
|   | A37       | The Patents Act 1953 Exhibit "CRWB5."   |
|   | A38       | The Patents Act 1953 Exhibit "CRWB6."   |
|   | A39       | Poitiek <i>et al.</i> , "Comparison of formoterol, salbutamol and salmeterol in methacholine-induced severe bronchoconstriction" $\beta_2$ -Agonists In Methacholine-Induced Bronchoconstriction", Eur Respir J., 13:988-992, 1999. |
|   | A40       | Rabe <i>et al.</i> , "Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomized controlled, double-blind study," Lancet, 368:744-753, 2006.                                    |
|   | A41       | Rabe <i>et al.</i> , "Budesonide/Formoterol in a Single Inhaler for Maintenance and Relief in Mild-to-Moderate Asthma," Chest, 129:246-256, 2006.   |

|  |                 |
|--|-----------------|
| Examiner Signature   | Date Considered |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |

|   |  |  |                                      |
|---|--|--|--------------------------------------|
| Substitute Form PTO-1449<br>(Modified)  | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br><b>06275-150003</b> | Application No.<br><b>10/010,283</b> |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary) |  | Applicant<br><b>Carl-Axel Bauer et al.</b>   |                                      |
|   |  | Filing Date<br><b>November 13, 2001</b>      | Group Art Unit<br><b>1617</b>        |
| (37 CFR § 1.98(b))  |  |  |                                      |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |   |
|---|-----------|---|
| Examiner Initial  | Desig. ID | Document  |
|   | A42       | Rees, "β <sub>2</sub> Agonists and asthma," BMJ, 302:1166-1167, 1991.   |
|   | A43       | Rosenborg <i>et al.</i> , "Relative systemic dose potency and tolerability of inhaled formoterol and salbutamol in healthy subjects and asthmatics," Eur J. Clin Pharmacol., 56:363-370, 2000.                  |
|   | A44       | Rodrigo <i>et al.</i> , "Inhaled Flunisolide for Acute Severe Asthma," Am J Respir Crit Care Med, 157:698-703, 1998.  |
|   | A45       | Rodrigo <i>et al.</i> , "Acute Asthma in Adults: A Review," Chest, 125:1081-1102, 2004.   |
|   | A46       | Ryrfeldt <i>et al.</i> , "Pulmonary disposition of the potent glucocorticoid budesonide evaluated in an isolated perfused rat lung model," Biochem Pharmacol., 38:17-22, 1989.                                  |
|   | A47       | Schuh <i>et al.</i> , "A Comparison of Inhaled Fluticasone and Oral Prednisone For Children with Severe Acute Asthma," New England Journal of Medicine, 343:689-694, 2000.                                      |
|   | A48       | Sears <i>et al.</i> , "Regular inhaled beta-agonist treatment in bronchial asthma," Lancet, 336:1391-1396, 1990.  |
|   | A49       | Shepherd <i>et al.</i> , "Regular Versus Symptomatic Aerosol Bronchodilator Treatment of Asthma," Br. J. Dis. Chest, Vol. 75, pages 215-217 (1981).   |
|   | A50       | Sue <i>et al.</i> , "A Comparison of Intravenous Hydrocortisone, Methylprednisolone, And Dexamethasone in Acute Bronchial Asthma," Annals of Allergy, 56:406-409, 1986.   |
|   | A51       | Sykes <i>et al.</i> , "A study of the duration of the bronchodilator effect of 12 ug and 24 ug of inhaled formoterol and 200 ug inhaled salbutamol in asthma," Respir. Med., 84:135-138, 1990.                  |
|   | A52       | Tan <i>et al.</i> , "Systemic Corticosteroid Rapidly Reverses Bronchodilator Subsensitization induced by Formoterol in Asthmatic Patient," Am. J. Respiratory and Critical Care Medicine, 156:28-35, 1997.      |
|   | A53       | Tattersfield <i>et al.</i> on behalf of the Facet International Study Group, "Exacerbations of Asthma," Am J Respir Crit Care Med, 160:594-599, 1999.   |
|   | A54       | The Dialog Corporation, "Formoterol launched in Switzerland", Accession No: S002557609000, 10/31/1990.  |
|   | A55       | The Merck Manual of Diagnosis and Therapy, 16 <sup>th</sup> edition, 1992, page 653.  |
|   | A56       | Trechsel, "Foradil in medical practice: 7 case studies," Ciba-Geigy Limited, Switzerland (1992).  |
|   | A57       | Treschel, AM Conference Report, A new long-acting beta-stimulator   |
|   | A58       | U.S. Department of Health and Human Services, "Practical Guide for the Diagnosis and Management of Asthma," October 1997 NIH Publication No. 97-4053.   |
|   | A59       | Vanzieleghem <i>et al.</i> , "A comparison of budesonide and beclomethasone dipropionate nasal aerosols in ragweed-induced rhinitis," J. Allergy Clin. Immunology, 79:887-892, 1987.                            |
|   | A60       | Waalkens <i>et al.</i> , "Budesonide and terbutaline or terbutaline alone in children with mild asthma: effects on bronchial hyperresponsiveness and diurnal variation in peak flow," Thorax, 46:499-503, 1991. |
|   | A61       | Wallin <i>et al.</i> , "Formoterol, a new long acting beta <sub>2</sub> agonist for inhalation twice daily, compared with salbutamol in the treatment of asthma," Thorax, 45:259-261, 1990.                     |

|  |                 |
|--|-----------------|
| Examiner Signature   | Date Considered |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |